Immediate Display DMB

Display Date 11-14-02@1:54 pm
Publication Date 11-18-02
Certifier M. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. This meeting was announced in the **Federal Register** of October 18, 2002 (67 FR 64400). The amendment is being made to reflect a change in the *Date and Time* and *Agenda* portions of the meeting. The meeting was originally scheduled for November 18 and 19, 2002. However, due to administrative complications, the discussions on November 19, 2002, will be postponed until a later date. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2002 (67 FR 64400), FDA announced that a meeting of the Peripheral and Central Nervous System Drugs Advisory Committee would be held on November 18

oc02299

3907

NM-2

and 19, 2002. On page 64400, in the second column, the *Date and Time* and *Agenda* portions of the meeting are amended to read as follows:

Date and Time: The meeting will be held on November 18, 2002, from 8 a.m. to 5 p.m.

Agenda: On November 18, 2002, the committee will discuss the role of brain imaging as an outcome measure in phase 3 trials of putative therapeutic drugs for Alzheimer's disease; the discussions will not focus on specific drugs or on specific applications to the agency. The agency is considering whether brain imaging modalities can be utilized as surrogate markers; that is, as primary outcomes in definitive clinical trials to measure drug effect in lieu of clinical outcomes. The committee will specifically discuss the following issues in reference to each imaging modality:

1. How is the surrogate imaging modality best validated?

2. If one uses an imaging modality to support a disease-modifying effect claim, how does one establish that such an effect occurs?

3. Has any surrogate imaging modality been validated at the present time?

4. Even if no surrogate imaging modality has currently been validated, is it appropriate to use one or more such modalities as primary or ancillary outcome measures of efficacy in phase 3 clinical trials?

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 11-13-02
November 13, 2002.

William Hubbard

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Dawn P. Hawkins